Council for Responsible Nutrition
1828 L Street, NW, Suite 810 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

Comments of CRN, delivered by Steve Mister, CRN President & CEO

FDA Public Hearing: Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

May 31, 2019

Good afternoon. My name is Steve Mister and I'm the President of the Council for Responsible Nutrition. CRN is the leading trade association representing the dietary supplement and functional food industry. We appreciate the opportunity to share our views with you today on creating a legal pathway to market for CBD.

I want to begin by acknowledging that we have heard FDA loud and clear: FDA currently considers CBD to be prohibited for use in dietary supplements or food because of the exclusionary provision in section 321-ff-3-B, a provision sometimes referred to as the NDA and IND exclusion. This provision was included in DSHEA to protect the commercial interests of pharmaceutical firms and to incentivize drug development by assuring that years and millions of dollars of research for a drug would not be diminished by allowing food and dietary supplements to use an article if it was first studied as a drug. It's important to recognize that this provision is grounded in protecting the commercial interests of pharmaceutical research—a worthy objective—but it is not a safety question, but rather a race to market…or more appropriately, a race to investigate.

Even so, FDA was given discretion by the statute to overrule that general canon. Congress expressly gave FDA this authority to permit an article to be used in food and supplements irrespective of the race to investigate, because it foresaw that circumstances might arise that would justify mutual use of the article and deny the indefinite monopoly to a drug company should the article have intended uses outside of drug claims.

So it is worth reiterating that the IND Exclusion is NOT a safety question. FDA has plenty of processes and standards in place to examine the safety of any ingredient, and it should use those tools and aggressively demand evidence of safety, but the initial determination whether CBD is a dietary ingredient is not a safety question. FDA needs to trust its own processes for examining safety in due time with respect to the requirements for each of its regulatory channels, whether food, cosmetic, supplement, OTC drug, or prescription medications.

One of the advantages of considering the definitional issue first—and independent of safety—is that it allows FDA to move quickly to clear up the regulatory confusion and then to consider the safety of each individual product rather than trying to adopt an across-the-board dosage ceiling applicable across all products. Such a broad safety standard, developed at the beginning of the process, would be ill-fitted for the vast range of CBD containing products already in the market, would fail to provide flexibility as new research emerges, and would not take into account the wide range of dosage forms, delivery systems, dosage levels, opportunities to provide cautionary labeling statements, and other differences among products that factor into whether they are considered to be safe. For FDA and for industry, consumer safety is always JOB ONE, but that doesn't mean sequentially it's the first job. Providing a predictable and lawful path to market is.

Particularly when it comes to products that are already in the marketplace, FDA needs to act swiftly. The agency must also act boldly to assure these products comply with the rules for whatever regulatory lane they are swimming in. If a CBD containing product is marketed as a dietary supplement, contains a dietary supplement statement of identity on the label, or carries a Supplement Facts box, the marketer of that product has implicitly signaled to FDA and to consumers that it should be held to the regulatory framework of dietary supplements. These products should, for example, be made in a facility registered with FDA, and subject to GMP inspection, the label should comply with all general regulations for supplements, the marketer should have in place a system for identifying, recording and reporting adverse events, any structure-function claims should be noticed to FDA, and all CBD-containing supplements should be treated as new dietary ingredients, subject to notification. Questions about product identify, purity, potency and composition should be addressed adequate characterization of the products in the NDI notification, followed up with product testing during inspections. FDA should strongly enforce these category-wide requirements for CBD products, as they would for any dietary supplement, using tools like warning letters, import alerts, product seizures, mandatory recall, and even criminal sanctions to send a clear message.

FDA will still have the opportunity to evaluate safety. While I will not get into the specific safe levels identified by ongoing research, FDA should find some comfort that well-respected authoritative reviews have found CBD to be safe. Demanding adherence to the NDI notification requirement in DSHEA gives FDA ample opportunity to insist upon, to analyze and to evaluate the safety data specific to each product formulation.

Indeed, CBD research has already resulted in several systematic reviews that support the potential for CBD to be used in the general population without the requirement of intervention from a healthcare professional. These early studies have found CBD is well tolerated and are appropriate for use.

Ironically, if a company submits an NDI notification to FDA today, complete with safety data, it will have that notification returned unread because the ingredients is not recognized as a legitimate dietary ingredient. If FDA creates a predictable path to market, the safety research that the agency so craves will materialize. The nutrition community, academia, government agencies like NIH and industry itself will join in a symphony of research.

So in summary, CRN urges FDA to act quickly and decisively. To resolve the definitional issues first by conducting a Notice & Comment rulemaking to allow hemp and hemp-derived CBD to be used in food and diet, and in the meantime, to demand that products marketed as dietary supplements or as food comply with all the other requirements long-established and expected of any product in those channels. Thank you.

#####